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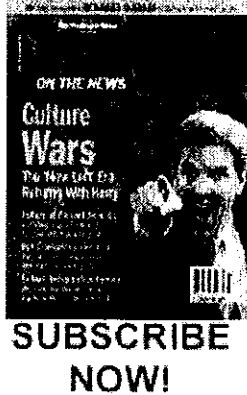
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## HEPATITIS B VACCINE - Ounce of Prevention, Pound of Misery?

By Aimee Howd

Published: Monday, March 22, 1999

When nurses gave her newborn son another injection, the room filled with the sound of his healthy cry. Julianne Jack recalls wondering through the haze of her postlabor exhaustion what that one was for. In fact, it was the hepatitis B vaccine, which Ohio mandated for all its newborns - a safe inoculation without known side effects, according to the Centers for Disease Control and Prevention, or CDC, in Atlanta.

But as she took her tiny firstborn into her arms again, coaxing him to nurse, Jack sensed something disturbing in the sound of his cry, the strange restlessness of his movements, a sudden yellowing of his skin. It was a relief when he seemed to slip into peaceful stillness in her arms. Just 27 hours old, she remembers thinking. She daydreamed of the future for their family of three until the night nurse came to return the baby to his crib. Something in his appearance as the nurse lifted him from her arms, however, tore a cry from her throat: "What's wrong with him?"

The nurse rushed Brandon out of the room and down the hall in search of help. After an hour, bed-bound by the lingering effects of an epidural, Jack faced the news alone: Little more than an hour after receiving the hepatitis B vaccination, her baby was dead.

No explanation was offered. The mystified coroner marked the cause of death unknown. Two years later a death certificate still has not been issued.

In Jack's eyes, the chain of events that day in the hospital implicates the vaccination. Brandon's doctors, though they voluntarily waived the family's medical bills, deny any such connection. The lawyer whose help the family enlisted to obtain copies of the medical records sent a letter saying the Jacks had no case against any of the medical professionals involved because he could find "no reports of any serious reaction to the vaccination."

In fact, "no confirmed reactions" is the standard line of federal officials in most cases, although since 1990 more than 24,000 reports of

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possible adverse reactions to the hepatitis B vaccine have been registered with the Food and Drug Administration's Vaccine Adverse Event Reporting System, or VAERS, including a significant number of severe injuries and deaths.

Federal guidelines issued in 1991 recommending three doses of the vaccine for health professionals coming into contact with blood, at-risk groups including intravenous drug users and people with multiple sex partners - and every child born after 1990 - remain unchanged. At least 35 states mandated the vaccine for entrance to kindergarten by 1996, and in 1977 the Advisory Commission on Immunization Programs reported vaccination of 84 percent of America's 19- to 35-month-olds.

In January 1999, the CDC further expanded its goals, calling for universal immunization of children up to age 18. Government agencies and pharmaceutical groups categorically deny that the VAERS reports are cause for alarm, explaining that the purpose of the data collection merely is to reveal unexpected patterns, that the adverse-reaction numbers may be inflated due to double reporting and that no scientific data prove the vaccine is the cause of the problems.

"Bad things happen to people all the time. It's unfortunate that we don't know the causes of many of those," says Neal Halsey, a leader in the American Academy of Pediatrics and director of the vaccine safety center at Johns Hopkins University in Baltimore. But Barbara Fisher, founder of the watchdog group National Vaccine Information Center, or NVIC (on the World Wide Web at [www.909shot.com](http://www.909shot.com)), objects. "Why can no one confirm or deny a causal relationship in these tens of thousands of adverse reports?" she asks. "Because the kind of scientific studies that could reveal the link have not been done." And, alas, they haven't.

"When vaccine coverage reaches high levels like they do in the U.S., essentially anyone with a negative medical event will have previously been vaccinated," Robert Chen of the CDC's National Immunization Program tells Insight. His solution to the dilemma raises the eyebrows of privacy advocates. "What is needed is a database with all vaccinations and all medical events linked in a large cohort to see if those vaccinated recently are more likely to develop the adverse event of interest," he says. "The CDC has established such a cohort with 5 million members of four large staff-models [health-maintenance organizations] on the West Coast in the Vaccine Safety Data Link Study."

Other approaches also are being examined. Bonnie Dunbar, a professor of cell biology at Baylor College of Medicine in Texas, is a leader among the growing number of scientists who are joining consumer advocates, parents'-rights groups and undiagnosed patients in searching for answers about adverse reactions to the vaccine.

To Dunbar and her colleagues, preliminary evidence indicates some people might be genetically disposed to an adverse autoimmune or neurological response to the recombinant hepatitis B vaccine. In an

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open letter last November, Dunbar wrote, "After carrying out extensive literature research on this vaccine, it is apparent that the serious adverse side effects of this vaccine may be much more significant than generally known (or admitted)."

Halsey tells Insight he doubts the credibility of people questioning the vaccine. But Dunbar's 25 years as a research scientist and medical-school professor and her National Institutes of Health honors for pioneering work in contraceptive vaccines are sturdy credentials.

Today's recombinant hepatitis B vaccine derives from a surface protein of the virus molecule. Dunbar suggests that similarities between the antigen and proteins in human nerves and tissues could trick the autoimmune systems of the genetically susceptible into attacking themselves. In Science magazine last summer, Halsey scoffed at that theory, asking how a fragment of virus protein used in a vaccine could cause symptoms not even caused by the virus.

Dunbar explains that any part of a virus molecule introduced into the human body can be met by a unique immune response. "The same rigorous testing [is required] every time you change the vaccine. The companies don't want to hear that because it is going to cost them a lot of money."

William Hildebrand, an immunogeneticist at the University of Oklahoma, plans to take a close look at the five or six genes that are responsible for controlling the immune response. Three observations lead him to conjecture that an individual's HLA genotype may mediate how he or she responds to the vaccine: Almost all negative responses occur in Caucasians, the number of genes determining autoimmune responses varies from race to race and the reported adverse responses are consistently autoimmune in nature. "It justifies asking what are the reactions and how frequent are they," Hildebrand says, "and that's all I would argue needs to be done at this time. If you understand which genes are involved in the adverse response, you can begin to understand the adverse response."

Until the research is done, however, Hildebrand remains skeptical of both sides of the debate. "One side is saying you can't prove [a cause-and-effect relationship]. The other side is saying, 'You know something is going on here.' I say let's find out. If you say that the world is flat and you don't do research, maybe the world will stay flat."

Denied government grants, funding for this research is being supplied by private donations, often from patients and surviving families. The initiatives of the inquiring scientists are important to bewildered survivors such as the Jacks, who have moved to Pennsylvania where they have been assured they can obtain a medical exemption for a second child they are expecting this summer. For two years they believed they were alone in their suspicions about the vaccine. Then a friend told them about an investigation and televised report by the TV newsmagazine 20/20.

While searching for the Internet version of the TV report, Jack found contact information for a father who had appeared on the show. That man is Michael Belkin, a New York financial adviser whose search for answers after his 5-week-old daughter died hours after her vaccination led him to apply his statistical training from the University of California at Berkeley to the tangled web of epidemiological studies at the core of the hepatitis B vaccination controversy.

Does the risk/reward ratio for administering the hepatitis B vaccine to the typical American baby justify the national vaccine mandate? Even questions about the incidence of the disease are difficult to answer. For example, 1996 and 1997 issues of the CDC's Morbidity and Mortality Weekly Reports, or MMWR, show only about 10,000 cases of hepatitis B reported in the United States. Yet the CDC estimates the total annual incidence of the disease at 150,000 to 300,000. The CDC believes the vast majority of cases go unreported because the hosts are asymptomatic or mistake the reaction for the flu.

Undoubtedly, asymptomatic chronic infection by the disease (which studies show is more likely to occur the earlier the virus is contracted) can lead to devastating cancers or cirrhosis late in life. Marketing materials for the vaccine produced by the International Task Force on Hepatitis B Immunization and the Program for Appropriate Technology in Health begin by warning doctors that three-quarters of the world's population lives in high- or midrange risk areas for hepatitis B and that the virus causes up to 80 percent of the world's liver-cancer deaths.

The materials claim a need for mass vaccination in the United States despite low endemicity in most of the nation: Certain narrow populations, such as Alaska natives, Southeast Asian immigrants, gay men and others experience moderate to high levels of infection.

But according to the CDC's figures, among infants, only those born to mothers infected with the virus are at any measurable risk for the disease. Belkin estimates that his daughter, like other infants of the average American family, had a .001 percent chance of contracting the disease. Of the 279 total reported cases of hepatitis B infection in American children under the age of 14 (as documented in a 1996 issue of MMWR), only 54 of those cases occurred in the newborn to 1-year-old age group in a total of 3.9 million babies born in the United States that year.

The need for American children born to families without the disease to receive the vaccine hinges, in most cases, upon their likelihood of engaging in promiscuous sexual behavior or sharing drug needles later in life. But even if this is satisfactory justification, Belkin notes, no conclusive evidence exists to indicate that immunity lasts beyond 10 years. Therefore, the inoculation would appear to protect only the sexually promiscuous and heroin-addicted under age 10.

Despite the unified rhetoric of government and industry officials, the roar of the victim mice is being picked up by mainstream media. Reports on the possible dangers of hepatitis B vaccinations have

appeared not only on 20/20 but in the Washington Post, the Chicago Tribune, Gannet News Service and Science, among others.

Infants are not the only ones in whom adverse events or reactions have been reported. Dunbar began to look into adverse reactions when her adult brother and her lab assistant each experienced autoimmune or neurological dysfunction after they were injected with the vaccine as professional precautions. Dunbar tells Insight that she personally hears each day from an average of four people who believe they were injured as a result of the hepatitis B vaccine.

One of them was Eric Jeffries, a former Fulbright scholar at Cambridge and a young father on his way to the top in the banking industry. He tells Insight that he was vaccinated prior to a tropical vacation but four days later began experiencing severe autoimmune dysfunctions ranging from fever, headaches and extreme pain to rashes and gastrointestinal troubles. He immediately thought of the vaccine, but a phone call to his doctor assured him the vaccine is not associated with adverse reactions. As his condition deteriorated, he was tested for everything from rheumatoid arthritis to fibromyalgia and AIDS. Finally, a doctor seconded his suspicion that, whatever the disorder, it had been triggered by the vaccine. Today, no longer able to work or even to walk, Jeffries still is looking for answers.

Betty Fluck was told that she needed to have the hepatitis B vaccine when she returned to her work as a registered nurse after taking a few years off to raise her three boys. Just hours before the vaccine was administered, she was helping to run her three school-age sons' soccer games with her husband, a coach, and was working on her yellow belt in karate. On Dec. 2, 1997, she received the vaccine. Twelve hours later she suffered severe pain, a high fever, swollen joints and respiratory problems. Until her fever broke, Fluck lost the use of her legs. "At the time," she says, "the damage was already done or started. I didn't know at that point what the whole disease process was."

As did so many other victims, Fluck went from doctor to doctor until one finally told her that the symptoms might indicate a reaction to the hepatitis B vaccine. But vaccine manufacturers repeatedly told her that they never had seen problems like this. As months passed, Fluck needed a walker, and by September 1998 she required full leg braces and elbow crutches to get around. Now she receives weekly intravenous gamma-globulin treatments for severe demyelination (a progressive condition in which the sheath surrounding and protecting human nerves deteriorates).


Since Fluck's brief appearance on the 20/20 episode, she says, "Every day I hear people with stories that are just like mine and doctors telling them it can't be the vaccine. Essentially, we're write-offs. Just the casualties of war [on disease]."

This month Fluck testified before an Indiana state Senate hearing considering whether to set a July 1999 mandate for all children to receive the vaccine before they enter kindergarten. As a result of the

hearings, the committee tabled the bill and voted unanimously to recommend that the vaccine be administered only at the parents' request.

For now, the federal health bureaucracy devotes its resources primarily to expanding and enforcing its mass vaccination policies rather than to evaluating adverse reports. Samuel Katz of the Vaccine Initiative of the Infectious Disease Society of America called Insight from the Atlanta airport enroute from the February 1999 ACIP conference where his colleague, Chen, of the CDC's National Immunization Program, presented an update on hepatitis B recommendations. Katz said the committee "reaffirmed the value of the vaccine" and of "moving ahead with the program to vaccinate children, teenagers and adults at risk."

But the French and Canadian governments already are funding research on hepatitis B adverse-event reports, says Dunbar. "There are many of us who are not going to go away." And Congress should take notice.

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